Pharmaceutical Sciences, 66, no. 1, Jan. 1977, p. 1-19). The Examiner indicates that the 35 U.S.C. 103 (a) rejection is being maintained for the reason of record filed on September 24, 2007. Applicants would like to point out that the Examiner rejected only claims 1-2 and 5-6 in the rejection of September 24, 2007 and the earlier rejection of January 29, 2007. It is factual error to finally reject claims 1-2 and 5-21 based on earlier non-final rejections of only claims 1-2 and 5-6. Accordingly, Applicants assert that the final rejection of claims 7-21 is inappropriate and should be withdrawn.

With regard to the final rejection of claims 1-2 and 5-6 under 35 U.S.C. 103 (a) based on *Bryans et al.* and *Berge et al.*, *Berge et al.* explicitly state "that there is no reliable way of predicting the influence of particular salt species on the behavior of the parent compound." The Examiner completely ignores this statement in *Berge et al.* and then concludes there is a reasonable expectation of successfully forming gabapentin tannate when *Berge et al.* is combined with *Bryans et al.* which merely disclose the parent compound, gabapentin, for use in treating sleep disorders.

Apparently, the Examiner believes that the invention of the present application is directed to the use of gabapentin tannate to treat sleep disorders. The Examiner repeatedly states that it would be obvious to the skilled artisan in the art to be motivated to use tannate for the salt of gabapentin for sleep disorders. See Final Rejection, page 5, paragraph 3, lines 5 and 6; and page 6, paragraph 1, lines 6-8. The claims at issue, 1-2 and 5-6, never mention sleep disorders. Furthermore, nowhere in the entire specification of the present application is there any mention of using gabapentin tannate to treat sleep disorders.

Equally lacking in relevance is the Examiner's statement that "regarding the reasonable expectation of success for the combined prior art, *Bryans et al.* expressly discloses gabapentin derivatives having the following uses (see col. 1, lines 22-26):

> protective effect against cramp induced by thiosemicarbazide; protective action against cardiazole cramp; the cerebral diseases, epilepsy, faintness attacks, hypokinesia, and cranial traumas; and improvement in cerebral functions. "

Where in claims 1-2 and 5-6 is there any mention of the use of gabapentin to treat any disease?

The Examiner then states that "gabapentin has nitrogen and a carboxyl group in the chemical compound" and its salt possible forms are described in the following (*Bryans et al.*, see col. 10, lines 33-37):

> Since amino acids are amphoteric, pharmacologically compatible salts when R is hydrogen can be salts of appropriate inorganic or organic acids, for example, hydrochloric, sulphuric, phosphoric, acetic, oxalic, lactic, citric, malic, salicylic, malonic, maleic, succinic, methanesulfonic acid,

The Examiner is merely emphasizing what is already known by one having ordinary skill in the art. The Applicants were well aware that gabapentin had a nitrogen and a carboxyl group. The Applicants explored even further and noted that the proximity of the amino (nitrogen) group to the carboxyl group was particularly challenging for one considering the formation of a gabapentin tannate salt. More specifically, it was thought that the negative charge on the carboxyl group may shield and possibly neutralize the positive charge on the proximal nitrogen, thus preventing the ionic interaction thought necessary for the formation of a gabapentin tannate salt. When one considers this in light of the well known and judicially accepted unpredictability of chemical reactions (see for example, *In re Joseph D. Fisher* 57 C.C.P.A. 1099; 427 F.2d 833; 1970 CCPA LEXIS 345; 166 U.S.P.Q. (BNA) 18, *Warner-Lambert Company et al. v. TEVA Pharmaceuticals USA, Inc.*, 418 F.3d 1326; 2005 U.S. App. LEXIS 16880; 75 U.S.P.Q.2d (BNA) 1865, and *The Regents of the University of California v. Eli Lilly and Company*, 119 F.3d 1559, 1997 U.S. App. LEXIS 18221; 43 U.S.P.Q.2d (BNA) 1398), it is specious, at best, for the Examiner to state that it would have been obvious to the skillful artisan to be motivated to use tannate to make a gabapentin salt. The fact that *Berge et al.* list tannate as one of many FDA approved salts is inconsequential. This is particularly true when Berge et al also acknowledges "that there

is no reliable way of predicting the influence of particular salt species on the behavior of the parent compound."

Applicants again respectfully submit that the Examiner has failed to establish a prima facie case of obviousness in the rejection of claims 1-2 and 5-6 based on *Bryans et al.* and *Berge et al.* for the reasons set forth in Applicants' Amendment submitted January 11, 2008, which is incorporated herein by reference.

Applicants also wish to highlight again, the inefficient prosecution history in this case. Applicants are attaching hereto a summary of the "Prosecution History" for the present application to illustrate the tortuous path taken by the Examiner in the examination of this case.

Based on the arguments submitted herewith, Applicants respectfully request reconsideration of the final rejection of claims 1-2 and 5-21 and urge the Examiner to proceed with a Notice of Allowance.

Respectfully submitted,
KING & SCHICKLI, PLLC

By: _____
Warren D. Schickli
Registration No. 31,057

247 N. Broadway
Lexington, KY 40507
(859) 252-0889